K080811

JUN 20 2008

510(k) Summary – Roche Tina-quant Cystatin C, Calibrator and Control Set

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

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Submitter name, address, contact

Roche Diagnostics
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Indianapolis IN 46250
(317) 521-7637

Contact person: Kerwin Kaufman

Date prepared: May 30, 2008

Device Name

Assay:
Proprietary name: Tina-quant Cystatin C
Common name: Cystatin C
Classification name: Test, Cystatin C

Calibrator:
Proprietary name: Cfas (Calibrator for automated systems) Cystatin C
Common name: Cystatin C calibrator
Classification name: Calibrator, secondary

Control:
Proprietary name: Cystatin C Control Set
Common name: Cystatin C Quality control material (assayed)
Classification name: Single (specified) analyte controls (assayed and unassayed)

Device Description

Assay:
The Roche Tina-quant Cystatin C is an immunoturbidimetric assay for the quantitative in vitro determination of cystatin C in human serum and plasma on Roche automated clinical chemistry analyzers.

The test principle is a particle enhanced immunoturbidimetric assay. Human cystatin C agglutinates with latex particles coated with anti-cystatin C antibodies. The precipitate is determined turbidimetrically.

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510(k) Summary – Roche Tina-quant Cystatin C, Calibrator and Control Set, Continued

Device Description (continued)	Calibrator: Cfas Cystatin C is a liquid, ready-for-use calibrator based on pooled delipidated human serum enriched with recombinant human cystatin C produced in E. Coli. Single level calibrators with lot specific values are diluted on board the analyzer to create a 6-point calibration curve. Control: Cystatin C Control Set contains 2 controls based on pooled delipidated human serum enriched with human recombinant cystatin C produced in E. Coli. The adjusted concentrations of the control component are in the low concentration range for Control Low and the elevated concentration range for Control High.
Intended use	Assay: Immunoturbidimetric assay for the quantitative in vitro determination of cystatin C in human serum and plasma on Roche automated clinical chemistry analyzers. Calibrator: Cfas (Calibrator for automated systems) Cystatin C is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets. Control: Cystatin C Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Predicate Device	We claim substantial equivalence to the DakoCytomation Cystatin C Immunoparticles, Cystatin C Calibrator Kit and Cystatin C Control Set cleared in 510(k) K041627.
Substantial equivalency – Reagent	The table below provides a comparison of the predicate device, DakoCytomation Cystatin C Immunoparticles (K041627) and the new device, Roche Tina-quant Cystatin C.

Feature	Predicate device: DakoCytomation Cystatin C Immunoparticles (K041627)	New Device: Roche Tina-quant Cystatin C
Intended Use/ Indications for Use	For in vitro diagnostic use. For professional use only. Cystatin C Immunoparticles are intended for the quantitative determination of cystatin C in human serum, heparinized plasma and EDTA plasma by turbidimetry and nephelometry. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal diseases.	Immunoturbidimetric assay for the quantitative in vitro determination of cystatin C in human serum and plasma on Roche automated clinical chemistry analyzers. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal diseases.
Specimen type	Serum, heparinized plasma, EDTA plasma	Serum and Lithium-heparinized plasma
Method	Particle enhanced immunoturbidimetric assay	Same
Traceability / Standardization	The cystatin C value assignment has been carried out by turbidimetry using a precise transfer protocol ensuring traceability to a pure recombinant cystatin C reference preparation, where the cystatin C concentration was established by dry mass determination.	This method has been standardized against an in-house reference preparation of pure recombinant human cystatin C. The cystatin C concentration of this reference preparation was established by dry mass determination as described in reference.
Reagent Storage	2 – 8°C	2 – 8°C
Calibrator	DakoCytomation Cystatin C Calibrator, single level Diluted to form a 6-point calibration curve	C.f.a.s. Cystatin C Calibrator, single level Diluted to form a 6-point calibration curve
Quality control	DakoCytomation Cystatin C Control Set, 2-level	Cystatin C Control Set, 2-level
Expected values	Individuals 1-50 years: 0.55-1.15 mg/L Individuals > 50 years: 0.63-1.44 mg/L	Same
Analyzers	Hitachi 911, Hitachi 917, MODULAR P, Cobas Mira Plus and IMMAGE	Hitachi 917, MODULAR P, and cobas c 501
Measuring Range	~0.4 – 7.5 mg/L	0.4 – 8.0 mg/L
Method comparison with Dako predicate	Passing Bablok: $y = 1.009x + 0.019$ $\tau = 0.96$ Linear regression: $y = 1.014x + 0.011$ $r = 0.999$ N=94, Range of X = 0.61-6.05 mg/L	

Precision	Total CV: 2.1% @ 3.95 mg/L 2.6% @ 0.96 mg/L 5.9% @ 0.45 mg/L 2.0% @ 1.71 mg/L 2.3% @ 5.37 mg/L	Within run CV: 0.91% @ 4.48 mg/L 0.97% @ 0.95 mg/L 1.71% @ 0.75 mg/L 0.67% @ 5.14 mg/L Total CV: 2.50% @ 4.35 mg/L 3.13% @ 0.94 mg/L 3.76% @ 0.73 mg/L 2.36% @ 4.98 mg/L
Limitations	Bilirubin, conjugated: No interference was found for conjugated bilirubin up to 600 mg/L (60 mg/dL). Bilirubin, unconjugated: No interference was found for unconjugated bilirubin up to 600 mg/L (60 mg/dL). Hemoglobin: No interference was found for hemoglobin up to 10 g/L (1000 mg/dL). Triglyceride: No interference was found for triglyceride up to 15 g/L (1500 mg/dL). Rheumatoid Factor: No interference was found for rheumatoid factor up to 1200 IU/mL. No antigen excess is found for cystatin C concentrations below 28 mg/L (the highest concentration tested). All drugs described in reference 7 were investigated according to the recommendations in reference 7. No interference was observed.	Icterus: No significant interference up to an I index of 60 (approximate conjugated and unconjugated bilirubin concentration: 60 mg/dL or 1026 µmol/L). Hemolysis: No significant interference up to an H index of 700 (approximate hemoglobin concentration: 700 mg/dL or 435 µmol/L). Lipemia (Intralipid): No significant interference up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. Rheumatoid factors < 1200 IU/mL do not interfere. A high-dose hook effect may occur at cystatin C concentrations >20.0 mg/L. Drugs: No interference was found at therapeutic concentrations using common drug panels (see references 18 and 19 in labeling). In very rare cases gammopathy, in particular type IgM Waldenström's macroglobulinemia), may cause unreliable results.

Substantial equivalency – Calibrator

The table below provides a comparison of the predicate device, DakoCytomation Cystatin C Calibrator (K041627) and the new device, Cfas (Calibrator for automated systems) Cystatin C.

Feature	Predicate device: DakoCytomation Cystatin C Calibrator (K041627)	New Device: Roche Cfas (Calibrator for automated systems) Cystatin C
Intended Use	Cystatin C Calibrator is intended for establishing calibration curves for the quantitative immunological determination of human cystat C by turbidimetry or nephelometry.	Cfas (Calibrator for automated systems) Cystatin C is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.
Analyte	Cystatin C	Same
Matrix	A liquid pool of delipidated human serum enriched with recombinant human cystatin C produced in E. coli and preservative.	Same
Storage	2 – 8 °C	Same

Substantial equivalency – Control Set

The table below provides a comparison of the predicate device, DakoCytomation Cystatin C Control Set (K041627) and the new device, Roche Cystatin C Control Set.

Feature	Predicate device: DakoCytomation Cystatin C Control Set (K041627)	New Device: Roche Cystatin C Control Set
Intended Use	Cystatin C Control Set is an assayed bi-level control intended to monitor and evaluate the precision and accuracy of the quantitative immunological determination of human cystatin C by turbidimetry or nephelometry.	Cystatin C Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Analyte	Cystatin C	Same
Matrix	2-level set with low and high cystatin C levels, based on liquid pools of delipidated human serum enriched with recombinant human cystatin C produced in E. coli and preservative.	Same
Storage	2 – 8 °C	Same

Performance evaluation

The Hitachi 917 Cystatin C test system was evaluated for several performance characteristics described within the submission.

In addition, the traceability, value assignment process, and stability of the Cfas Cystatin C calibrator and Cytatin C Control set are described.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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JUN 20 2008

Re: k080811
Trade Name: Tina-Quant Cystatin C
Regulation Number: 21 CFR 862.1225
Regulation Name: Test, Cystatin C
Regulatory Class: Class II
Product Codes: NDY, JIT, JJX
Dated: March 21, 2008
Received: March 24, 2008

Dear Kerwin Kaufman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080811

Device Name: **Roche Tina-quant Cystatin C, Calibrator and Controls**

Indications For Use:

Reagent:

Immunoturbidimetric assay for the quantitative in vitro determination of cystatin C in human serum and lithium-heparin plasma on Roche automated clinical chemistry analyzers. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal diseases.

Calibrator:

Cfas (Calibrator for automated systems) Cystatin C is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets.

Control:

Cystatin C Control Set is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Prescription Use XXX AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C. Benson
Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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